K042563

FEB 2 3 2005

Durex Play Warmer™, Premarket Approval [510(k)] Summary

Section VIII.1 Submitter Information

SSL Americas
3585 Engineering Dr.
Suite 200
Norcross, GA 30092-9214
Phone: 770 – 582 – 2222
Fax: 770 – 582 – 2233
Contact person: Chris Robinson, Regulatory Affairs Manager, SSL Americas
Date of Summary: June 6th 2004

Section VIII.2 General Device Information

Device Trade Name: Durex Play Warmer™
Device Common Name: Personal lubricant
Classification: Patient lubricant

Section VIII.3 Predicate Devices

K-Y Jelly Personal Lubricant (K955648)
AstroGlide (K935299)

Section VIII.4 Device Description

Durex Play Warmer™ is a clear colorless personal lubricant composed of Purified Water, Hydroxyethyl Cellulose (Natrosol 250), Propylene Glycol, Benzoic Acid, Sodium Hydroxide, Sodium Saccharin, Glycerol.

Section VIII.5 Intended Use

Indications: Durex Play Warmer™ is intended as a moisturizer for vaginal dryness and personal lubrication of the vaginal entry to enhance condom use and to facilitate ease and comfort during intimate sexual activity.

Section VIII.6 Substantial Equivalence

Durex Play Warmer™ is substantially equivalent in intended use to K-Y Jelly personal lubricant and AstroGlide and similar in composition. All products are marketed as personal lubricants, safe to use with condoms, water soluble and sold Over-the-Counter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 3 2005

Mr. Chris Robinson
Controller Head of Global Regulatory Affairs
SSL Americas, Inc.
3585 Engineering Drive, Suite 200
NORCROSS GA 30092-2222

Re: K042563
Trade/Device Name: Durex Play™ Warmer™ Personal Lubricant
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Product Code: 85 HIS
Regulatory Class: II
Regulation Number: 21 CFR §880.6375
Regulation Name: Patient lubricant
Product Code: 80 KMJ
Dated: February 3, 2005
Received: February 9, 2005

Dear Mr. Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042563

Device Name: Durex Play Warmer Personal Lubricant

Indications For Use:

Durex Play™ Warmer™ is intended as a moisturizer for vaginal dryness and personal lubrication of the vaginal entry to enhance condom use and to facilitate ease and comfort during intimate sexual activity.

Prescription Use _____ AND/OR Over-The-Counter Use ____X__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042563